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Attorney's Docket No.: 00786-625006

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Applicant : Vladimir P. Torchilin et al.
Serial No. : 10/081,223
Filed : February 22, 2002

Art Unit : 1642
Examiner : Susan Ungar, Ph.D.

Title : NUCLEOSOME-BASED ANTI-TUMOR COMPOSITIONS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attached to this facsimile communication cover sheet is an Urgent Communication of Requested Data, faxed this 28th day of March, 2005, to the United States Patent and Trademark Office.

Respectfully submitted,

Date: March 28, 2005

Reg. No. 54,112
For Lee Crews, Ph.D.
Reg. No. 43,567

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Vladimir P. Torchilin *et al.* Art Unit : 1642
Serial No. : 10/081,223 Examiner : Susan Ungar, Ph.D.
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URGENT COMMUNICATION OF REQUESTED DATA

Applicants thank Examiner Ungar for discussing the present application in a telephone call on September 1, 2004, with their representatives Lee Crews and Todd Garcia. Examiner Ungar suggested that, to overcome the rejection for lack of enablement, Applicants would have to provide data showing that the method claimed was effective in an animal model even if the animals used had antinuclear autoantibodies (ANAs) in their circulation at the beginning of the study.

This communication provides the Examiner with the requested data. Filed herewith is a declaration signed by Dr. Vladimir P. Torchilin ("the Declaration"). In the Declaration, Dr. Torchilin describes studies showing that one can inhibit malignant cell growth in a mammal at risk for such growth by administering nucleosomes to the mammal The data further show that one can inhibit malignant cell growth even if anti-nuclear autoantibodies (ANAs) are already present in the mammals when the nucleosomes are administered (*see* the Declaration at ¶ 3). The two tumor cell lines used (NCI-H82 and PC-3), the preparation of the nucleosomes, and the schedule of their administration is described in the Declaration at ¶ 4. The levels of ANAs in the nucleosome-treated animals were measured approximately every five days, beginning on the day the animals received the first dose of nucleosomes (the Declaration at ¶ 5). The levels of ANAs in the blood of comparable mice that were injected with tumor cells but not with nucleosomes ("the control animals") were also measured (the Declaration at ¶ 5). ANAs were present in the

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March 28, 2005
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Scott Barrett
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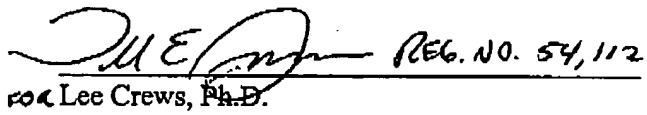
circulation of both the nucleosome-treated animals and the control animals (the Declaration at ¶ 5). At the initial measurement, the ANA titre in the nucleosome-treated animals and the control animals was essentially the same (the Declaration at ¶ 5). Over time, the ANA titre in the nucleosome-treated animals increased about five-fold, while ANAs remained detectable in control animals at about, or somewhat above, their initial level (the Declaration at ¶ 5). The average volume and average weight of the tumors in the nucleosome-treated animals was consistently less than the average volume and average weight of the tumors in the control animals (the Declaration at ¶ 6).

The results support Dr. Torchilin's conclusion that one can inhibit malignant cell growth in a mammal at risk for such growth by administration of nucleosomes (the Declaration at ¶ 8). Moreover, ANAs were present in both the nucleosome-treated animals and the control animals at the beginning of the study and it was when those levels were boosted by administration of nucleosomes that malignant cell growth was inhibited (the Declaration at ¶ 8).

Applicants respectfully request that the pending claims be allowed. No fees are believed to be due at this time. If there are any fees, or credits, please apply them to Deposit Account No. 06-1050, referencing Attorney Docket No. 00786-625006.

Respectfully submitted,

Date: 3/28/05



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